

Notice of Allowability

Application No.

09/889,520

Examiner

Deborah A Davis

Applicant(s)

RAVEN ET AL.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment response of May 7, 2004.
2. ☒ The allowed claim(s) is/are 1-6, 9-11 and 19 (renumbered 1-10).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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DETAILED ACTION

1. Applicants' response to the Office Action mailed on February 9, 2004 has been acknowledged. Currently, claims 1-6, 9-11 and 19 are allowed. Claims 7-8 and 12-18 has been cancelled.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Frank Cottingham on October 15, 2004.

3. IN THE CLAIMS:

DELETE CLAIM LANGUAGE OF CLAIMS 1-6, 9-11 AND 19 AND REPLACE WITH AMENDED LANGUAGE:

1. (Currently amended) An assay for an analyte, comprising contacting the analyte with a thermostable reporter adenylate kinase coupled to a binding agent specific for the analyte, wherein a complex is formed, adding ADP and testing for formation of ATP wherein, prior to the addition of ATP, endogenous kinase and uncomplexed thermostable reporter adenylate kinase is substantially removed by washing and,

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residual endogenous kinase is inactivated by heating, wherein the amount of said ATP formed correlates to the concentration of the analyte.

2. (previously presented) The assay of Claim 1, wherein the amount of thermostable reporter adenylate kinase complexed with the analyte is substantially proportional to the amount of analyte.
3. (previously presented) The assay of Claim 1, wherein formation of ATP is measured using luciferin/luciferase.
4. (currently amended) An assay for determining the presence and/or amount of an analyte in a sample, comprising exposing the sample to a thermostable reporter adenylate kinase coupled to a binding agent specific for the analyte, so that the reporter adenylate kinase is specifically associated with any analyte present in the sample via the binding agent; removing thermostable reporter adenylate that is not bound to analyte; exposing said thermostable reporter adenylate kinase bound to the analyte to ADP; and testing for formation of ATP, wherein prior to addition of ADP, residual kinase other than thermostable reporter adenylate kinase is substantially removed by heating.
5. (previously presented) The assay of Claim 1, comprising further adding an ATPase to the analyte and removing the ATPase from the analyte prior to adding ADP.

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6. (previously presented) The assay of Claim 5, wherein the ATPase is inactivated by heating the ATPase.

9. (currently amended) An assay for determining presence and/or amount of an analyte in a sample comprising:

exposing the sample to a detector compound, the detector compound comprising an antibody specific to the analyte coupled to a thermostable enzyme; isolating (i) detector compound that has specifically bound to analyte from (ii) detector compound that has not specifically bound to analyte; determining the presence and/or amount of detector compound that has bound to analyte by adding a substrate for the thermostable enzyme and measuring a product formed by conversion of said substrate to said product by said thermostable enzyme; therein prior to adding the substrate non-thermostable enzymes are destroyed by application of heat.

10. (previously presented) The assay of Claim 9, wherein the enzyme is adenylate kinase and the substrate is ADP, the ADP is converted into ATP by the thermostable enzyme.

11. (previously presented) The assay of Claim 10, wherein background ATP compound is removed by the addition of ATPase prior to adding ADP.

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19. (previously presented) An assay for an analyte, comprising the steps:
- (a) specifically binding the analyte with a thermostable reporter kinase which has been coupled to a binding agent specific for the analyte forming a complex;
 - (b) washing to remove endogenous non-thermostable kinase and thermostable reporter kinase not bound to analyte;
 - (c) heating to inactivate endogenous kinase not removed by step (b); and
 - (d) adding ADP and testing for formation of ATP.

The following is an examiner's statement of reasons for allowance: The prior art neither teaches nor suggest a thermostable reporter adenylate kinase or thermostable enzyme coupled to an antibody or binding agent wherein residual and endogenous kinase is destroyed by the application of heat.

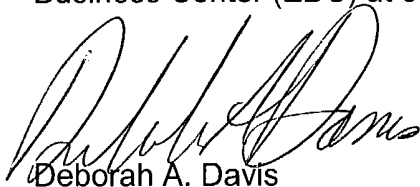
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

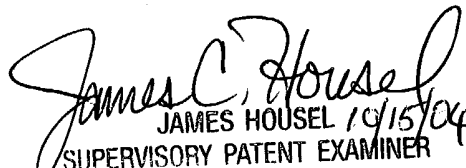
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah A. Davis
Remsen Bldg.
Room 3D58
October 15, 2004



JAMES HOUSEL 10/15/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600